No. 23-10640

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRADLEY SANDERS, *et al.*,

Personal-Injury Plaintiffs,

v.

AJANTA PHARMA USA, INC., *et al*.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
MDL No. 2924

GENERIC DEFENDANTS-APPELLEES' CORRECTED ANSWERING BRIEF

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Generic Defendants-Appellees hereby certifies that the previously filed Certificate remains correct.

Dated: July 26, 2024

Respectfully submitted,

/s/ Thomas J. Yoo

STATEMENT REGARDING ORAL ARGUMENT

Generic Defendants-Appellees respectfully request oral argument because of the extensive procedural history and issues involved in this MDL proceeding and in Personal-Injury Plaintiffs' initial brief. Oral argument will assist the Court in resolving these issues.

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[1] Pursuant to 11th Cir. R 28-1(e), the cases upon which Generic Defendants primarily rely on are marked with an asterisk (*).

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STATEMENT REGARDING
ADOPTION OF BRIEFS OF OTHER PARTIES

The Generic Defendants adopt by reference the brief of the Brand Defendants-Appellees (filed July 25, 2024). Fed. R. App. P. 28(i); 11th Cir. R. 28-1(f). Specifically, the Generic Defendants adopt Brand Defendants-Appellees' Argument as to The District Court Had Subject Matter Jurisdiction. *Id.*

STATEMENT OF JURISDICTION

These are appeals from cases that were consolidated for pretrial proceedings pursuant to 28 U.S.C. § 1407 before the United States District Court for the Southern District of Florida. MDL.Dkt.1; *see* MDL.Dkt.2512:3; MDL.Dkt.3750:3–4.[2] As all Plaintiffs attested in their individual short form complaints as well as the relevant master complaints, the district court had subject-matter jurisdiction based on diversity of citizenship under 28 U.S.C. § 1332(a). *E.g.*, *Cagle v. Boehringer Ingelheim Pharm., Inc. et al*, Case No. 9:20-cv-80991, Doc. 1 ¶ 8 (S.D. Fla. June 23, 2020) (short form complaint of plaintiff Dennis Cagle) ("Jurisdiction is proper upon diversity of citizenship."); *see* MDL.Dkt.887¶216 ("This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). In each of the actions there is complete diversity among Plaintiffs and Defendants …."); MDL.Dkt.2759¶220 (same).

This Court has appellate jurisdiction under 28 U.S.C. § 1291 because the district court entered final judgments.

[2] This brief refers to MDL docket entries as "MDL.Dkt." and refers to docket entries in this Court's appellate docket (all of which refer to docket entries in appeal No. 21-12618) as "CA11.Dkt." In accordance with Eleventh Circuit Local Rule 28-5, this brief cites to all record documents, other than transcripts, using the document's internal pagination.

INTRODUCTION

The Personal-Injury Plaintiffs in these consolidated appeals allege that the heartburn medications Zantac and its generic form, ranitidine, have an inherent propensity to form a carcinogen, N-nitrosodimethylamine ("NDMA"), which they contend caused their cancer. Some Personal-Injury Plaintiffs sued the various manufacturers of generic ranitidine ("Generic Defendants") along with other categories of defendants.

Applying the Supreme Court's landmark *Mensing* and *Bartlett* opinions,[3] the district court held that all of Personal-Injury Plaintiffs' state-law claims against Generic Defendants in an initial master complaint and amended master complaint were barred by impossibility preemption. Plaintiffs' individual actions and short-form complaints, however, remained alive (if only just) until the district court reached the issue of general causation. Addressing motions to preclude and for summary judgment filed by Brand Defendants, the district court carefully examined the opinions of all the causation experts that Plaintiffs disclosed for the five "designated" cancers Plaintiffs' Leadership had chosen to pursue. The court found that each expert failed to meet the standard set by *Daubert*[4] and Federal Rule of Evidence 702.

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[3] *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013).

[4] *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

Personal-Injury Plaintiffs' brief is a hodgepodge of irrelevant arguments and disagreements with the district court's exclusion of experts who each offered improper and unreliable opinions. Personal-Injury Plaintiffs make virtually no argument regarding the district court's jurisdiction and dismissal of claims against Generic Defendants based on preemption, using nearly all of their 27,970 words on the district court's order addressing the expert witnesses presented by Personal-Injury Plaintiffs. Despite Personal-Injury Plaintiffs asking for and receiving separate briefs and expanded word counts on the preemption and *Daubert* issues, they seek to incorporate arguments from the separate Generic-Only brief here. That directly contravenes this Court's briefing Order. Therefore, those arguments are improper and should be ignored.

In addition to the vitriol and *ad hominem* attacks on the district court judge, Personal-Injury Plaintiffs suggest that when an expert regurgitates phrases such as "Bradford-Hill criteria" and "dose response," the district court must rubber-stamp those opinions as admissible and of assistance to the jury. They ignore the fact that Fed. R. Evid. 702 not only allows, but requires, the court to consider the application of methodologies and the opinions they generate.

Personal-Injury Plaintiffs began this Multidistrict Litigation ("MDL") by manufacturing claims when a lab affiliated with the plaintiffs' bar heated ranitidine to over 200 degrees Fahrenheit, conditions far outside any scientifically valid testing

standards and ones that have been rejected by the U.S. Food and Drug Administration as unreliable. Despite later disavowing any reliance on this flawed data, MDL leadership for Personal-Injury Plaintiffs agreed to Fed. R. Evid. 702 hearings on the question of general causation: whether ranitidine causes certain cancers in humans. In the lead-up to those hearings, the district court entered multiple orders concerning the Fed. R. Evid. 702 challenges and *Daubert* hearing process. Personal-Injury Plaintiffs' Leadership consented to each one.

Following days of testimony, briefing and argument, the district court authored a well-supported 341-page decision excluding the general causation opinions of every expert Plaintiffs offered. The district court summarized the proper application of its gatekeeping function as follows:

> Here, there is no scientist outside this litigation who concluded ranitidine causes cancer, and the Plaintiffs' scientists within this litigation systemically utilized unreliable methodologies, with a lack of documentation on how experiments were conducted, a lack of substantiation for analytical leaps, a lack of statistically significant data, a lack of internally consistent, objective, science-based standards for the evenhanded evaluation of data.

MDL.Dkt.6120:7.

After excluding the Personal-Injury Plaintiffs' experts and granting summary judgment because plaintiffs lacked sufficient evidence to establish general causation, the district court turned to the applicability of its ruling to other cases in the MDL. MDL.Dkt.6120:299. The district court established an Order to Show Cause

process—a well-established procedure used in multiple MDLs—to permit other plaintiffs to come forward with additional evidence and experts. No plaintiff came forward with new experts or evidence. Considering the plaintiffs' experts at the *Daubert* hearing relied on studies of general application, such as animal testing and exposures of rubber plant workers, it is not surprising that no plaintiff took the district court up on its offer. Given plaintiffs' failure to come forward with new evidence despite ample opportunity to do so, the district court properly extended its dismissal order.

Despite their inability to present reliable expert opinions and their failure to respond to the district court's Order to Show Cause process, Personal-Injury Plaintiffs filed this appeal. The district court's opinions are thorough, well-reasoned and based on the proper application of the Supremacy Clause and Fed. R. Evid. 702. They requires affirmance.

STATEMENT OF THE ISSUES

1. Did the district court have diversity jurisdiction over Personal-Injury Plaintiffs' actions?

2. Did the district court correctly dismiss Personal-Injury Plaintiffs' claims as preempted?

3. Did the district court act within its discretion in excluding Personal-Injury Plaintiffs' general causation experts based on the experts' unreliable methodologies and conclusions?

4. Did the district court act within its discretion in extending its *Daubert* ruling to later-filed plaintiffs who put forth no general causation expert of their own?[5]

STATEMENT OF THE CASE

Despite the lack of scientific evidence connecting the clinical use of ranitidine to any real-world cancer risk in humans, plaintiffs around the country began filing lawsuits in 2019 claiming they developed cancer from taking ranitidine. This appeal arises out of an MDL created pursuant to 28 U.S.C. § 1407 to coordinate pretrial proceedings in those lawsuits, which was assigned to Judge Robin Rosenberg. MDL.Dkt.1.

I. Overview of the MDL

This appeal involves certain claims set out in two master complaints: the Master Personal Injury Complaint ("MPIC") (MDL.Dkt.887) and the Amended Master Personal Injury Complaint ("AMPIC") (MDL.Dkt.2759). The MPIC and AMPIC raise claims of alleged labeling and design defects concerning generic forms

[5] Personal-Injury Plaintiffs' Initial Brief raises two additional issues directed toward Brand Defendants. As those issues are not directed to the Generic Defendants, they are not addressed in this brief. The Brand Defendants have addressed those issues.

of the drug commonly known as Zantac, which is used to treat heartburn and gastric problems. The molecule in question—ranitidine—is the active ingredient in both Zantac and its generic forms. The MDL initially involved claims against companies that allegedly manufactured ranitidine products under the brand name Zantac ("Brand Defendants"), manufactured generic ranitidine products ("Generic Defendants"), distributed ranitidine products ("Distributor Defendants"), sold ranitidine products ("Retailer Defendants"), or repackaged ranitidine products ("Repackager Defendants").

Prior to this litigation, Zantac had been on the market for about 35 years. In 1983, the U.S. Food and Drug Administration ("FDA") approved the sale of prescription Zantac. MDL.Dkt.887¶¶226,231,432. Starting in 1995, the FDA approved the sale of various forms of over-the-counter ("OTC") Zantac. MDL.Dkt.887¶¶233,237. When the patents on prescription and OTC Zantac expired, numerous generic drug manufacturers started to make generic ranitidine products in prescription and OTC forms. MDL.Dkt.887¶¶249–51.

II. The District Court Found that Personal-Injury Plaintiffs' Claims Are Preempted by Federal Law

From the outset of the MDL, the district court appointed leadership for both the plaintiffs and the defendants to assist in the management of the thousands of cases in the MDL. MDL.Dkt.685; MDL.Dkt.721. The district court scheduled several hearings at the beginning of the MDL with the respective leadership teams.

MDL.Dkt.958; MDL.Dkt.959; MDL.Dkt.960; MDL.Dkt.961. At the May 2020 initial case management hearing, both parties agreed that the "threshold question" for all of the cases in the MDL was whether ranitidine could cause cancer in humans. MDL.Dkt.960:162. In fact, one member of plaintiffs' leadership explained that the *Daubert* motions on general causation—i.e., whether ranitidine caused cancer—would occur immediately after the close of discovery and before any bellwether or individual case work-up occurred. MDL.Dkt.960:193. Reflecting the parties' understanding of the case, the district court's case management order states that "[t]he Court adopts the parties' proposed schedule that a hearing on *Daubert* challenges on general causation will precede bellwether selection, and general causation *Daubert* motions shall be filed 18 months following the initiation of discovery." MDL.Dkt.1194:2.

Plaintiffs filed three rounds of Master Complaints as well as individual Short Form Complaints.[6] On June 22, 2020, Plaintiffs filed the first Master Complaint, the MPIC, suing Brand Defendants, Generic Defendants, Distributor Defendants, Retailer Defendants, and Repackager Defendants. MDL.Dkt.887; MDL.Dkt.888; MDL.Dkt.889. The MPIC brought twelve substantive and three derivative counts

[6] Pretrial Order #31, section (II)(B)(5), states, "For each action directly filed in or transferred to MDL No. 2924 subject to this Order, the Master Personal Injury Complaint together with the Short Form Complaint shall be deemed the operative Complaint." MDL.Dkt.876.

against Generic Defendants. *See* MDL.Dkt.2512:5,52. Each count incorporated allegations that: 1) NDMA formation is intrinsic to all ranitidine products; 2) the ranitidine molecule itself contains the constituent molecules to form NDMA; and 3) NDMA forms at room temperature and whenever ranitidine is digested. MDL.Dkt.887¶¶105–148. And each count alleged that Generic Defendants were liable for failing to: 1) warn of the presence of NDMA; or 2) change the products' basic chemical design to eliminate the propensity to form NDMA. *See, e.g.,* MDL.Dkt.887¶456 ("Defendants had a continuing duty to warn Plaintiffs of dangers associated with ranitidine"); ¶485 ("Defendants could have designed ranitidine-containing products to make them less dangerous."). Plaintiffs also alleged that ranitidine was misbranded, and therefore illegal to sell under federal law, but only because of labeling deficiencies. MDL.Dkt.887¶¶421–423 None of the counts alleged that state law prohibited Generic Defendants from selling ranitidine products due to the risks posed by NDMA.

Generic Defendants filed a motion to dismiss the MPIC, arguing that the Plaintiffs' claims against them were preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"). MDL.Dkt.1582. On December 31, 2020, the district court dismissed all claims against the Generic Defendants as preempted, but granted Personal-Injury Plaintiffs leave to amend. MDL.Dkt.2512:7; MDL.Dkt.2515:13–14.

Personal-Injury Plaintiffs thereafter filed the Amended Master Complaint, the AMPIC. In the AMPIC, Plaintiffs asserted claims against the Generic Defendants for "Failure to Warn Through Expiration Dates," "Negligent Product Containers," "Negligent Storage and Transportation," "Negligent Failure to Test," and "Failure to Warn Through the FDA." MDL.Dkt.2759¶¶932–62,1371–1405,1949–71,1984–98,2433–59. All Plaintiffs' claims in the AMPIC were based on the same factual allegations as those in the MPIC, including that ranitidine medications are inherently defective due to their propensity to form NDMA and no ranitidine is safe to ingest. *See, e.g.,* MDL.Dkt.2759¶¶343,953. While Plaintiffs alleged that the Generic Defendants should have taken steps to shorten expiration dates, change containers, add testing, or store the products differently, none of those steps would prevent NDMA formation and render ranitidine safe to consume.

Generic Defendants again argued that these claims were preempted. MDL.Dkt.3750:8. On July 8, 2021, the district court dismissed all claims in the AMPIC against the Generic Defendants with prejudice based on preemption. MDL.Dkt.3750.

The Generic Defendants moved for entry of final judgment in all cases naming Generic Defendants. MDL.Dkt.3933. The motion requested entry of final judgment pursuant to Rule 58(a) in all individual cases that named only Generic Defendants, i.e., "Generic-Only Cases," and entry of final judgment pursuant to Rule 54(b) in

individual cases that named a Generic Defendant and one or more Defendants from another category of Defendants, i.e., "Mixed-Generic Cases." MDL.Dkt.3933. The district court granted the Generic Defendants' motion in part. MDL.Dkt.4595. Specifically, the district court found that, "[i]n Generic-Only cases where the Plaintiffs have declined to amend their Short Form Complaints and have instead proceeded directly to appeal, the standard for Rule 58 is met and the Court will enter Rule 58 final judgment." MDL.Dkt.4595:24. The district court went on to state that "[i]n Generic-Only cases where the Plaintiffs have not filed a notice of appeal, however, there is still a theoretical possibility that the individual Plaintiff could obtain relief in this MDL" because "the deadline for the individual Plaintiffs to amend their Short Form Complaints has not passed." MDL.Dkt.4595:24. The district court declined to enter Rule 58 judgment in those cases "until such time as it is clear (1) that all of the relief sought in the Short Form Complaint was addressed in the Court's orders of dismissal on the master complaints, and (2) that the Plaintiff foregoes the right to amend the Short Form Complaint." MDL.Dkt.4595:24. The district court also declined to enter any form of judgment for the class complaints at that time. MDL.Dkt.4595:36.

On November 15, 2021, the district court entered final judgment in favor of the Generic Defendants in all Mixed-Generic Cases pursuant to Rule 54(b) because the district court found the decision sufficiently final and no just reason for delay.

MDL.Dkt.4664. The district court also entered final judgment in Generic-Only cases in which an appeal had been filed pursuant to Rule 58(a) because the plaintiffs declined to timely amend their short form complaint. MDL.Dkt.4664.

III. The District Court Concludes Personal-Injury Plaintiffs' Claims Lack Scientific Support

This litigation began because a company with ties to the plaintiffs' bar—Valisure—tested batches of ranitidine in various conditions and allegedly found NDMA above the FDA's daily limit of 96 nanograms, or ng.[7] To achieve this purported result, Valisure had to heat the ranitidine to a temperature of 266 degrees Fahrenheit. When Valisure tested ranitidine with a temperature of 98 degrees Fahrenheit, a biologically plausible temperature, Valisure detected no NDMA. MDL.Dkt.6120:3.

Faced with benign results at 98 degrees Fahrenheit, Valisure tested ranitidine's reaction with salt in an artificial stomach. However, Valisure once again used biologically implausible test conditions. The amount of salt Valisure used to generate NDMA was so great that it was close to the level where the salt intake

[7] Despite Personal-Injury Plaintiffs' claims about NDMA, smoked and grilled meats contain NDMA and those foods are lawful to sell and consume. The FDA's daily limit for NDMA intake is 96 ng per day. U.S. Food & Drug Admin., *Information About Nitrosamine Impurities in Medications*, <tinyurl.com/FDANDMA> ("[A] person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer").

would cause death. When Valisure tested ranitidine at a biologically plausible temperature with salt concentrations that a person could safely ingest, Valisure again detected no NDMA. MDL.Dkt.6120:3–4.

The motivation for Valisure to conduct such testing became clear immediately: the first of Personal-Injury Plaintiffs' lawsuits were filed simultaneously with Valisure sending its purported results to the FDA. Those lawsuits—and the MPIC—relied heavily upon Valisure's tests.[8]

Personal-Injury Plaintiffs also heavily relied on a study overseen by Stanford University, which reported NDMA levels in ranitidine nearly 500 times the acceptable daily limit. However, the Stanford University study was retracted by the study authors because, like Valisure, the Stanford laboratory had created NDMA as an artifact of the testing method. MDL.Dkt.6120:5. By the time of the district court's *Daubert* hearing, Personal-Injury Plaintiffs conceded that much of the data on ranitidine levels cited in their MPIC and AMPIC could not be relied upon in answering the general causation question. MDL.Dkt.6120:5–6.

[8] The MPIC misleadingly referred to Valisure's 266-degree heat as "modest" and the salt levels used by Valisure as "biologically relevant." MDL.Dkt.887¶¶326,329.

IV. The District Court Excludes Personal-Injury Plaintiffs' Experts Because of the Improper Application of Methodologies and Unreliable Findings

Based on the parties' agreement in the case management order that Rule 702 and *Daubert* challenges for general causation would be heard before any bellwether trial, the district court entered a briefing schedule for *Daubert* and science-related summary judgment motions. MDL.Dkt.5579. The motions focused on five Designated Cancers as the Plaintiffs did not offer any general causation experts on any other cancers (the Non-Designated Cancers.)[9]

On June 23, 2022, Brand Defendants filed three *Daubert* motions to exclude Personal-Injury Plaintiffs' general causation experts and a roadmap brief in support of their motions to exclude the general causation experts and for summary judgment. MDL.Dkt.5732; MDL.Dkt.5734; MDL.Dkt.5735; MDL.Dkt.5736. Brand Defendants argued that the district court should exclude the general causation opinions of Personal-Injury Plaintiffs' experts because the experts lacked reliable methodologies. MDL.Dkt.5736:5. Further, Brand Defendants argued that several of the expert opinions based on secondary methodologies, including *in vitro* and animal studies, were unreliable and, therefore, inadmissible. MDL.Dkt.5735. Finally, in the roadmap brief, Brand Defendants argued that if Personal-Injury

[9] Designated Cancers are bladder, esophageal, pancreatic, stomach and liver cancer. MDL.Dkt.6622:2 n.1.

Plaintiffs could not support general causation related to the Designated Cancers with admissible expert testimony, then the district court should grant summary judgment in favor of Brand Defendants. MDL.Dkt.5734. After the briefing was complete, the district court had oral argument over the course of three days—over 26 hours of argument—to ensure that all parties had the opportunity to present their argument to the district court. MDL.Dkt.6024; MDL.Dkt.6025; MDL.Dkt.6060.

On December 6, 2022, the district court entered an Omnibus Order granting Brand Defendants' *Daubert* motions on general causation. MDL.Dkt.6120. The district court framed general causation as follows: "Does the scientific evidence reliably demonstrate that ranitidine is capable of causing a Designated Cancer at the highest realistic exposure level any plaintiff may have experienced?" MDL.Dkt.6120:34. As the district court explained, the key inquiry to answer this question was the amount of NDMA in ranitidine. MDL.Dkt.6120:35. After a thorough review of all of the evidence that Personal-Injury Plaintiffs put forward, the district court concluded that the Personal-Injury Plaintiffs had failed to provide any reliable scientific evidence that ranitidine causes any of the five Designated Cancers because of NDMA or otherwise. MDL.Dkt.6120:35.

The district court then granted Brand Defendants' motion for summary judgment, holding that Personal-Injury Plaintiffs were unable to proceed on any of their claims because there was no reliable scientific evidence that ranitidine causes

any of the Designated Cancers and, thus, no proof that defendants or their ranitidine products had caused Personal-Injury Plaintiffs' damages. MDL.Dkt.6120:336. In fact, the district court noted that "[t]he Plaintiffs [had] conceded on the record that the Court should grant summary judgment for the Defendants if the Court granted all of the Defendants' *Daubert* motions." MDL.Dkt.6120:336n.170.

Additionally, the district court entered Pretrial Order #78, which gave individual Personal-Injury Plaintiffs a deadline of thirty days after the district court's final rulings on general causation to unilaterally amend their short form complaints without the need for leave of the court. MDL.Dkt.5580. The district court's "intent in setting this deadline [was] to afford individual Plaintiffs the opportunity to review the district court's general causation rulings before deciding whether to file any individualized claims pursuant to Pretrial Order #31, section (II)(b)(4)(n)." MDL.Dkt.5580:2–3. Notably, none of the individual Personal-Injury Plaintiffs amended their short form complaint in response to this Pretrial Order.

V. The District Court's Order to Show Cause Process

Almost one month after the district court's entry of summary judgment, the district court held a status conference and asked the parties which matters in the MDL still required adjudication. MDL.Dkt.6622:2. The two relevant issues to be decided were: (1) whether the district court's ruling on general causation at summary judgment for Brand Defendants was dispositive of general causation for non-Brand

Defendants[10]; and (2) whether the district court's ruling applied to cases filed after December 6, 2022—the date of the district court's *Daubert* and summary judgment order. MDL.Dkt.6622:2.

The district court then entered its first order to show cause asking Personal-Injury Plaintiffs why summary judgment should not be entered for Designated Cancers in favor of all Defendants. MDL.Dkt.6303. The district court first explained that any Non-Brand Defendant had standing to request entry of final judgment based on the *Daubert* ruling in the cases where the Non-Brand Defendant was named in the Short Form Complaint. MDL.Dkt.6303:9. The district court then set forth the basis for entry of final judgment in favor of the Non-Brand Defendants. MDL.Dkt.6303:9–10. Finally, the district court set a briefing schedule for the parties to respond to its order to show cause. MDL.Dkt.6320.

A few weeks later, the district court entered a second order to show cause why summary judgment should not be entered against all Personal-Injury Plaintiffs, regardless of the date the case was filed. MDL.Dkt.6444. In it, the district court stated:

> This Order serves as a Rule 56(f) notice, through an order to show cause process, and grants the Plaintiffs the opportunity to address why the Court should not enter summary judgment as to every Designated Cancer personal injury case in the MDL, regardless of the date the

[10] "Non-Brand Defendants" include Generic Defendants, Distributor Defendants, Retailer Defendants and Repackager Defendants.

> case was first filed, including cases filed on or after August 1, 2022, for [] all the reasons the Brand Defendants were previously found to be entitled to summary judgment.

MDL.Dkt.6444:8. Again, the district court walked through the case management procedure that allowed the district court to apply the rulings to all Personal-Injury Plaintiffs, the lack of evidentiary support to show ranitidine could cause cancer, and how Personal-Injury Plaintiffs were on notice that the general causation ruling would apply to all plaintiffs. *See generally* MDL.Dkt.6444. Finally, the district court again laid out a briefing schedule for the parties to respond to the order to show cause, including how individual Personal-Injury Plaintiffs could come forward with evidence to show why the summary judgment order should not be applied to their individual cases. MDL.Dkt.6444:16–17.

On April 17, 2023, Personal-Injury Plaintiffs' leadership team responded to the district court's orders to show cause. MDL.Dkt.6540. In the response, Personal-Injury Plaintiffs' leadership team never argued that there was new evidence or previously unknown evidence that they would like to present to the district court. MDL.Dkt.6540. Instead, they simply argued that the individual Personal-Injury Plaintiffs did not have the opportunity to present their own experts, that the MDL case management procedure did not give the district court the ability to apply its summary judgment ruling to all defendants, and that the district court did not have jurisdiction over the Non-Brand Defendants due to the pending appeals.

MDL.Dkt.6540. Notably, no Personal-Injury Plaintiff came forward by the district court's deadline to individually respond to the district court's orders to show cause. MDL.Dkt.6622:6.

On May 15, 2023, and pursuant to Rule 56(f), the district court entered summary judgment in favor of all Defendants—including Generic Defendants—for every Designated Cancer personal injury claim in the MDL. MDL.Dkt.6622.

VI. The District Court's Indicative Ruling Process

After the district court's ruling on general causation, Retailer Defendants and Distributor Defendants filed a motion for an indicative ruling pursuant to Federal Rule of Civil Procedure 62.1. MDL.Dkt.6233. The Retailer Defendants and Distributor Defendants asked the district court to rule that, if this Court were to remand jurisdiction to the district court, the district court would enter judgment on both preemption and *Daubert* grounds. MDL.Dkt.6233. The next day, Generic Defendants filed a motion for 58(a) final judgment in Generic-Only cases not pending appeal. MDL.Dkt.6237. Generic Defendants indicated that if the district court were inclined to grant the Retailer Defendants and Distributor Defendants' motion for an indicative ruling, Generic Defendants reserved the right to seek a modified judgment applying the general causation ruling to Generic Defendants. MDL.Dkt.6327:16n.4.

On March 2, 2023, the district court issued its ruling on Retailer Defendants and Distributor Defendants' motion for an indicative ruling. MDL.Dkt.6310. The district court said that if this Court were to remand the case to the district court, it would vacate its Rule 54(b) judgment in order to resolve any remaining issues and enter a single final judgment under Rule 58. MDL.Dkt.6310:2. Explaining its reasoning, the district court stated that the appeal has remained in substantially the same posture as when final judgment was entered in November 2021. MDL.Dkt.6310:12. Had the district court known that the MDL would proceed through rulings on general causation, *Daubert*, and summary judgment before appellate briefing had even begun, the district court said, its "analysis of the issues would have differed significantly, and it would not have had the same concerns regarding the different parties' abilities to join the appeal." MDL.Dkt.6310:12–13. The district court's original intent of "avoiding inefficient piecemeal appeals" was no longer being served by the Rule 54(b) certification. MDL.Dkt.6310:12–13. And to avoid "the inefficiencies of separate, piecemeal appeals," the district court held, should jurisdiction be returned, the district court would vacate its Rule 54(b) rulings in order to resolve any remaining issues and enter a single consolidated Rule 58 final judgment applicable to all claims and all parties in the MDL. MDL.Dkt.6310:13–14.

On March 16, 2023, Personal-Injury Plaintiffs objected to the request for indicative ruling and moved for this Court to retain its jurisdiction. They cited four reasons why this Court should not grant remand. In addition to erroneously claiming that Rule 62.1 "does not authorize" the district court's indicative ruling, Personal-Injury Plaintiffs claimed that the district court has improperly "telegraphed" its plan to enter summary judgment, Rule 62.1 is unconstitutional because it permits advisory opinions, and any error in the district court's original 54(b) judgment has been cured so remand is unnecessary. CA11.Dkt.298.[11] On September 8, 2023, this Court remanded the appeals to the district court on a limited basis for entry of the district court's indicative ruling over Personal-Injury Plaintiffs' objections. CA11.Dkt.333. Following the remand from this Court, the district court entered an order vacating prior entry of Rule 54(b) judgments and entering Rule 58 final judgment in all Designated Cancer cases.[12] MDL.Dkt.6974.

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[11] There are eight pending consolidated appeals: *Chandler v. Glenmark Pharmaceuticals Inc. USA et al.*, No. 21-12618; *Abdoo v. Glenmark Pharmaceuticals Inc. USA et al.*, No. 21-14325; *Sanders v. Ajanta Pharma et al.*, No. 23-10640; *Townsend v. GlaxoSmithKline et al.*, No. 23-11080; *Base v. Glenmark Pharmaceuticals Inc. USA, et al.*, No. 23-12584; *Neely v. Glenmark Pharmaceuticals Inc. USA et al.*, No. 23-13155; *Stoltz v. Glenmark Pharmaceuticals Inc. USA, et al.*, No. 23-13182; *Krause v. Glenmark Pharmaceuticals Inc. USA, et al.*, No. 23-13283.

[12] Additionally, the district court requested supplemental briefing on what steps were required to enter final judgment on the remanded Non-Designated Cancer cases. MDL.Dkt.6794. Following this briefing, the district court entered Rule 58 final judgment in the remaining Non-Brand, Non-Designated Cancer cases in accordance

VII. Plaintiffs' Request for Generic Only Briefing

On August 30, 2023, a subset of the Personal-Injury Plaintiffs—comprising 18 appellants who sued only Generic Defendants ("Generic-Only Appellants")—filed a motion for a briefing schedule. CA11.Dkt.332. Generic-Only Appellants requested that the Court set these cases for briefing and argument separately from the rest of the pending MDL appeals. CA11.Dkt.332.

On September 12, 2023, Generic-Only Appellants filed a reply in support of their motion stating that the other pending appeals will have "***nothing to do with preemption***" and that they had waited long enough for this Court to hear their appeals. CA11.Dkt.336 (emphasis added).

On October 18, 2023, this Court granted the 18 Generic-Only Appellant's motion and entered a briefing order. CA11.Dkt.340. That Order stated that "Briefing may proceed with respect to the appellants with Rule 58 judgments." Thereafter, on December 26, 2023, the Court entered an Order addressing motions to consolidate the appeals. CA11.Dkt.355-1.

That Order separated the appeals into distinct groups. First, this Court reiterated that "[t]he briefing as to the appellants with Rule 58 judgments in no. 21-12618 [the Generic-only cases], as referenced in the order dated October 18, 2023,

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with the limited remand from this Court. MDL.Dkt.7125. Personal-Injury Plaintiffs have not raised any arguments concerning the Non-Designated Cancers. All issues related to such cancers are deemed waived. *See infra* note 20.

shall remain separate from the briefing of other appellants." CA11.Dkt.355-1. Then, as to the appeals of the Personal-Injury Plaintiffs, the Order provided that "[t]he remaining plaintiffs-appellants should file the same, consolidated initial brief" and that "[e]ach of the three groups of defendants-appellees—the retailer and distributor defendants-appellees, the generic manufacturer defendants-appellees, and the brand manufacturer defendants-appellees—should file a single response brief on behalf of its group of defendants-appellees." CA11.Dkt.355-1. Finally, the Court's briefing order authorized the parties to "incorporate by reference" briefs filed in other appellate dockets in one narrow circumstance: The parties' briefs in the *Adams* class-action appeal "may incorporate by reference the consolidated briefing discussed below"—*i.e.*, "the same, consolidated initial brief" filed in multiple appellate dockets and subject to the double-length 28,000-word limit. CA11.Dkt.355-1:2–3. In sum, this Court provided both the Generic-Only and Personal-Injury Plaintiffs with the separate briefing they requested.

STANDARD OF REVIEW

This Court reviews legal questions and a district court's grant of a motion to dismiss de novo. *United States v. Dennis*, 26 F.4th 922, 926 (11th Cir. 2022); *Marrache v. Bacardi U.S.A., Inc.*, 17 F.4th 1084, 1091–92 (11th Cir. 2021); *Sebastian v. Ortiz*, 918 F.3d 1301, 1307 (11th Cir. 2019).

This Court reviews "for abuse of discretion the district court's decisions regarding the admissibility of expert testimony and the reliability of an expert opinion." *United States v. Frazier*, 387 F.3d 1244, 1258 (11th Cir. 2004). A district court's procedural decisions are likewise reviewed for abuse of discretion. *See Santiago v. Lykes Bros. S.S. Co.*, 986 F.2d 423, 427 (11th Cir. 1993).

SUMMARY OF THE ARGUMENT

Personal-Injury Plaintiffs have mischaracterized the basis for diversity jurisdiction, the application of impossibility preemption to claims asserted against the Generic Defendants, and the district court's gatekeeping function. Personal-Injury Plaintiffs' appeal lacks merit, and this Court should affirm the district court in all respects.

I. The Exercise of Diversity Jurisdiction in this MDL

These cases were properly before the district court based on diversity jurisdiction. As the district court correctly noted, use of a consolidated master pleading does not deprive the court of subject matter jurisdiction by destroying diversity. MDL.Dkt.4595:19 (citing *In re Bridgestone/Firestone, Inc., Tires Prod. Liab. Litig.*, 256 F. Supp. 2d 884, 890 (S.D. Ind. 2003) (finding that the filing of an MDL master complaint had "no effect" on potential subject matter jurisdiction arguments)). The district court determined that it did not "permanently merge[] the individual cases in this MDL—it has merely consolidated them, temporarily, for

pretrial purposes consistent with its mandate under 28 U.S.C. § 1407." MDL.Dkt.4595:19. Were it otherwise, almost every MDL would lack jurisdiction over its plaintiffs and section 1407 would be self-defeating.

II. Claims Against Generic Defendants Were Preempted

Claims against Generic Defendants in the MPIC and AMPIC were properly dismissed based on preemption. Personal-Injury Plaintiffs' claims against the Generic Defendants must be viewed against the backdrop of the federal legal framework for generic pharmaceuticals. Drug products, both prescription and OTC, are regulated under the FDCA, which is implemented and enforced by FDA. *See* 21 U.S.C. § 301, *et seq*.; *id*. at §§ 371, 393. In 1984, Congress passed the Hatch-Waxman amendments to the FDCA to expand access to affordable generic drugs by reducing barriers to generic market entry. Those amendments created the modern generic drug industry. *See Mensing*, 564 U.S. at 612–13, 626. Generic drug companies may file an Abbreviated New Drug Application ("ANDA") demonstrating the product's equivalence to a previously approved drug product. *Id*. at 612–13 (citing 21 U.S.C. §§ 355(b)(1), (d); 21 U.S.C. § 355(j)(2)(A)).

The FDCA requires ANDA applicants to show that their generic drugs contain the same active ingredients, employ the same route of administration, are in the same dosage form and the same strength, and "have the same therapeutic effect" as the branded equivalent on which their ANDA is based. *See* 21 U.S.C.

§§ 355(j)(2)(A)(i)–(iv). Those federal duties of "sameness" prohibit a generic manufacturer from making unilateral changes to a drug's design, manufacturing process, or clinical warnings in a label. *See Bartlett,* 570 U.S. at 477; *Mensing*, 564 U.S. at 618.

In *Mensing*, the Supreme Court held that federal law preempts state-law failure-to-warn claims against generic-drug manufacturers. 564 U.S. at 608–09. Two years later, the Supreme Court extended *Mensing* and held that federal law also preempts state-law design-defect claims against generic drug manufacturers. *Bartlett*, 570 U.S. at 475–76. The district court properly applied these principles in dismissing the MPIC and AMPIC claims against the Generic Defendants. MDL.Dkt.2512; MDL.Dkt.3750.

III. The District Court Excluded Unreliable Expert Testimony

The district court properly exercised its gatekeeping function under Fed. R. Evid. 702 and excluded the unsupported opinions of Personal-Injury Plaintiffs' experts. The proffered experts cherry-picked studies, improperly applied unreliable methodologies, and offered conclusions that no scientist outside of this litigation had ever reached. "[T]he burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citations omitted); *see also* Fed. R. Evid. 702 advisory

committee's notes to 2000 amendment ("[T]he proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.").

IV. Plaintiffs Have Forfeited Any Argument that the District Court Lacked Authority to Extend its Summary Judgment Ruling to Non-Brand Defendants.

Personal-Injury Plaintiffs' initial brief identifies six issues on appeal. I.B. at 10. None of those issues addresses the district court's extension of its *Daubert* ruling to Non-Brand Defendants, and Plaintiffs nowhere contend that the extension constituted an abuse of discretion. Their brief includes only one sentence asserting that they had previously told this Court that it should decline to remand appeals to the district court to revise the initial Rule 54(b) judgments, contending that the district court "lacked authority" to extend its summary judgment ruling to non-Brand Defendants. I.B. at 80. But this Court already considered *and rejected* that argument when it granted remand, specifically so that the district court could revise the existing judgment. Under the law of this Circuit, Personal-Injury Plaintiffs' conclusory and passing assertion that the district court lacked authority to extend its summary judgment ruling to Generic Defendants does not merit this Court's review. *See, e.g.*, *Anthony v. Georgia*, 69 F.4th 796, 807 (11th Cir. 2023).

V. The District Court Followed the Proper Procedure to Apply Its Daubert Ruling to All MDL Plaintiffs.

Having found that Personal-Injury Plaintiffs failed to satisfy their burden, the district court excluded the experts' general causation opinions and granted summary judgment. Through an order to show cause process, the district court determined that Personal-Injury Plaintiffs "failed to persuade the Court that there could be any meaningful general causation difference between Brand Defendants' ranitidine and non-Brand Defendants' ranitidine." MDL.Dkt.6622:19. As such, the district court properly entered final judgment in favor of the Generic Defendants based on both preemption and Personal-Injury Plaintiffs' failure to prove general causation.

ARGUMENT

I. The District Court Maintained Diversity Jurisdiction Over the Cases in the MDL

On April 10, 2024, Plaintiffs filed their initial briefs in the latest round of MDL appeals. For the first time in four years of litigation, Personal-Injury Plaintiffs claim that the district court lacked subject-matter jurisdiction over their cases. Initial Brief ("I.B.") at 26.[13]

[13] As discussed below, it is improper for Personal-Injury Plaintiffs to "incorporate" arguments from a brief they filed in a separate appeal into their initial brief in this appeal. *See infra* Argument § II.A. Whereas Plaintiffs' Initial Brief here impermissibly purports to incorporate another party's brief in a *different* appellate docket outside the narrow circumstances authorized by the Court's briefing order, this brief incorporates another party's brief in the *same* appellate docket. This latter approach is expressly authorized by Federal Rule of Appellate Procedure 28(i),

A. Personal-Injury Plaintiffs have adopted self-described "absurd" arguments

Personal-Injury Plaintiffs embrace the same arguments that they previously derided as "absurd" and "foreclosed" by "controlling" Supreme Court precedent. *Cartee*, No. 21-10305, Doc. 23, pp. 1, 9–17; CA11.Dkt.265:5–9.

Plaintiffs assert that their new view—i.e., that "the cases were merged"—is just "what the district court" and "Defendants have said all along." CA11.Dkt.376:20,21. The record does not support Personal-Injury Plaintiffs' new account of the pertinent procedural history. For example, in an earlier filing in this case, Personal-Injury Plaintiffs stated that the district court "ruled that the actions were *not* merged," and "[t]hat holding was . . . supported by most *Defendants* in the MDL." CA11.Dkt.265:12 (emphasis in original). Personal-Injury Plaintiffs also previously told this Court that "[e]ven if" merger destroyed diversity and "the district court's orders were ultra vires, the Court could—conceivably—sever each case on appeal to cure the jurisdictional defect." CA11.Dkt.265:3n.1 (citing authorities).

The record demonstrates that in the district court and on appeal, "the Generic Defendants argued that each member case in the Zantac MDL retained its individual status and was not 'merged' with every other case" for purposes of appellate finality

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which provides that in "a case involving more than one appellant or appellee, including consolidated cases, … *any party may adopt by reference a part of another's brief*." (emphasis added).

or diversity jurisdiction. CA11.Dkt.264:2 (citing MDL.Dkt.3895; MDL.Dkt.3922; MDL.Dkt.4149); CA11.Dkt.264:3 (explaining that the district court "did not 'permanently merge[] the individual cases in this MDL—it has merely consolidated them, temporarily, for pretrial purposes consistent with its mandate under 28 U.S.C. § 1407."); CA11.Dkt.264:9 ("There is no 'merging' of the parties for diversity purposes, even if there is 'merger' for appellate finality purposes pursuant to *Gelboim* footnote 3.").[14] Notably, Plaintiffs' initial brief omits any reference to remedies short of dismissal—including possibilities Plaintiffs themselves found "conceivabl[e]" in prior filings, before they lost on the critical issue of general causation. As that additional change-of-position underscores, Personal-Injury Plaintiffs' new theory of jurisdiction would allow them to relitigate their claims before different trial judges and negate the efficiencies achieved in the MDL, in which the district court skillfully resolved this issue.

[14] As this Court found in *Cartee*, the master pleading alone was *not* the operative pleading: "Mr. Cartee's operative complaint includes two documents: the MPIC and his SFC." *In Re Zantac (Ranitidine) Prod. Liab. Litig*., No. 21-10305, 2022 WL 16729151, at *4 (11th Cir. Nov. 7, 2022); *id.* at *5 ("Because there is no final ruling against his operative complaint—the combination of the MPIC and his SFC—to put the last nail in the coffin of his action, we lack jurisdiction to consider Mr. Cartee's appeal."); *id.* at *7 ("[A]t the moment there is no final ruling putting their operative complaints—the combination of the MPIC and their individual SFCs—to rest.").

B. The district court continuously treated the cases as separate

Personal-Injury Plaintiffs' argument that after the district court entered final judgment in the eighteen Generic-Only actions, the district court "treated the cases as merged." CA11.Dkt.376:21–22. But their examples prove the opposite. They argue that the district court declined to enter judgment in individual plaintiff Arthur Cartee's case based on its rulings on the MPIC. *see Chandler* I.B. 22, but that only confirms that the court viewed Mr. Cartee's individual case as separate. *See* MDL.Dkt.6317:1,4 (district court stating that it had "never … ruled on the legal sufficiency of Mr. Cartee's Short Form Complaint" and declining "to give Mr. Cartee's individual case special treatment").

Relatedly, Personal-Injury Plaintiffs' argument that the district court extended its *Daubert* ruling based on "law of the case" is a red herring. The district court relied on a comprehensive show-cause process to extend summary judgment in favor of Generic Defendants and to the actions of late-filing Personal-Injury Plaintiffs, not law of the case. The district court's Show Cause Order specifically refers to the Court's intent to "enter final judgment in many individual Plaintiff's [sic] ***cases***." MDL.Dkt.6444:16.[15] And when the district court ultimately did enter final judgment

[15] The district court was specifically addressing its intent to enter final judgment in cases where individual Plaintiffs had named Brand Defendants and summary judgment had been entered under *Daubert*. At the time, the show cause process was ongoing, and the district court had not yet decided to enter final judgment as to non-Brand Defendants, or individual Plaintiffs with later-filed cases.

that is precisely what it did do—it directed the Clerk of the district court to enter "approximately 14,000 Rule 58 final judgments," one in each individual plaintiff's respective docket. MDL.Dkt.6974:2.

In sum, the use of master complaints and short form complaints did not destroy diversity jurisdiction. *See, e.g., In re Bridgestone/Firestone, Inc. Tires Prod. Liab. Litig.*, 256 F. Supp. 2d 884, 890 (S.D. Ind. 2003) (finding that the filing of a master complaint had "no effect" on potential subject-matter jurisdiction arguments). Plaintiffs' attempts at jurisdictional manipulation do not require a different finding.

II. The District Court Correctly Held that Preemption Bars Plaintiffs' State-Law Claims

The district court correctly concluded that all claims against Generic Defendants are preempted by federal law. Personal-Injury Plaintiffs' initial brief asserts in passing that the district court erred in concluding that state-law claims against Generic Defendants, as set forth in the MPIC and the AMPIC, are preempted by federal law. I.B. at 27.

A. Personal-Injury Plaintiffs improperly incorporate arguments from the Generic-Only brief

In their initial brief, Personal-Injury Plaintiffs "incorporate the arguments made in the Generic-Only opening brief" concerning jurisdiction and preemption. I.B. at 27. This supposed incorporation, however, violates this Court's briefing order

of December 26, 2023, which was based on Generic-Only Appellants motion stating that the other appeals will have "***nothing to do with preemption.***" CA11.Dkt.336 (emphasis added). The Court's briefing order (1) kept the Generic-Only briefing "separate" from the other appeals and (2) authorized the parties to "incorporate by reference" briefs filed in other appellate dockets in one narrow circumstance: The parties' briefs in the *Adams* class-action appeal "may incorporate by reference the consolidated briefing discussed below"—*i.e.*, "the same, consolidated initial brief" filed in multiple appellate dockets and subject to the double-length 28,000-word limit. CA11.Dkt.336:2–3. Given these circumstances, judicial estoppel prevents the Personal-Injury Plaintiffs resorting to the expediency of adopting arguments by reference.

Judicial estoppel is an equitable concept that protects "the integrity of the judicial process by prohibiting parties from deliberately changing positions according to the exigencies of the moment." *New Hampshire v. Maine*, 532 U.S. 742, 749–50 (2001) (internal citations omitted). For judicial estoppel to apply, courts consider three factors: (1) whether a party has taken a position that is "clearly inconsistent" with an earlier position, (2) whether a party succeeded in persuading the tribunal to accept the earlier position, so that judicial acceptance of the inconsistent position creates the perception that the court was misled, and (3) whether acceptance of the inconsistent position would derive an unfair advantage to

the opposing party. *Id.* at 750–51. Each factor applies here as the Plaintiffs (1) originally asked for Generic-Only preemption briefing separate from the other appeals, (2) this Court entered an Order over the objections of Defendants establishing separate Generic-Only briefing and (3) Plaintiffs have gained an unfair advantage in having sought separate briefing with expanded word counts for some of the briefs.[16] Because Plaintiffs should be judicially estopped from incorporating arguments, the Court should deem Plaintiffs' preemption-based arguments as abandoned for purposes of all cases other than the Generic-Only cases in which those arguments were presented. *United States v. Campbell*, 26 F.4th 860, 873 (11th Cir. 2022) (en banc) (holding that issues not properly presented on appeal are deemed forfeited and will not be addressed absent extraordinary circumstances), *cert. denied*, 143 S. Ct. 95 (2022).

[16] This Court's briefing order did not authorize Personal-Injury Plaintiffs to unilaterally and substantially enlarge the (already expanded) word limit this Court imposed by resorting to the expediency of adopting arguments by reference. *Promptu Sys. Corp. v. Comcast Cable Commc'ns*, 92 F.4th 1384, 1386 (Fed. Cir. 2024) (holding that "(1) it is improper to incorporate material from one brief by reference into another unless in compliance with Fed. R. App. P. 28; (2) in no event is such incorporation permitted if it would result in exceeding the applicable word count"). *Accord Medtronic, Inc. v. Teleflex Life Scis. Ltd.*, 86 F.4th 902, 907 (Fed. Cir. 2023) ("According to its Certificate of Compliance, Medtronic's opening brief includes 13,979 words, yet it attempts to incorporate by reference twenty pages from another brief in another case, amounting to over 4,000 extra words. That is a clear violation of both the motions panel's order and our rules.") (internal citations omitted); *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 910 (Fed. Cir. 2014) ("It would be fundamentally unfair to allow a party to use incorporation to exceed word count.").

B. The district court correctly decided that Personal-Injury Plaintiffs' claims were preempted

Assuming this Court allows Personal-Injury Plaintiffs to circumvent its briefing order by adopting arguments by reference, Personal-Injury Plaintiffs' preemption arguments fail for the reasons set out in Generic Defendants' answering brief in the Generic-Only Appeals.

To briefly summarize, the Supremacy Clause of the U.S. Constitution provides that federal law "shall be the supreme Law of the Land, . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. "In accordance with that principle, when state law conflicts with federal law, state law must give way." *Guarino*, 719 F.3d at 1248. As the district court recognized, *Mensing* and *Bartlett* supply the framework for determining when federal law conflicts with state-law claims against generic pharmaceutical companies. *See, e.g.*, *Guarino v. Wyeth*, 719 F.3d 1245, 1248–49 (11th Cir. 2013); C*lub Madonna Inc. v. City of Miami Beach*, 42 F.4th 1231, 1253 (11th Cir. 2022) (explaining that this Court's conflict preemption analysis is guided by "the Supreme Court's treatment of a similar preemption claim"). In *Mensing* and *Bartlett*, the Supreme Court held that federal law preempts state-law failure to warn and design defect claims against generic drug manufacturers because they around bound by the federal "duty of sameness" to use the same labeling and design as the brand-name drug. The *Bartlett* Court also squarely rejected what it referred to as a "stop-selling"

argument: that a manufacturer could satisfy both its state- and federal-law duties by choosing not to make the FDA-approved medicine at all. This is because impossibility preemption jurisprudence "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* Any other interpretation "would mean that not only [*Mensing*], but also the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption, were wrongly decided." *Id.*

The district court correctly concluded that the MPIC's warnings- and design-based state-law claims are preempted under *Mensing* and *Bartlett,* because each count alleged that Generic Defendants were liable for failing to: 1) warn of the presence of NDMA; or 2) change the products' basic chemical design to eliminate the propensity to form NDMA. *See, e.g.*, MDL.Dkt.887¶456. And Plaintiffs' parallel misbranding theory – *i.e.*, that Generic Defendants could have complied with federal and state law by withdrawing ranitidine from the market earlier– cannot save their claims from preemption, for a number of reasons.

First, the misbranding theory was rejected in *Mensing* and multiple later decisions. *See, e.g., PLIVA, Inc. v. Mensing*, Case Nos. 09-993, 09-1039, and 09-1501 at 30 (U.S. Mar. 2011) (Brief of the United States as *amicus curiae*); *Mensing*, 564 U.S. at 617–18; *PLIVA, Inc. v. Mensing*, Nos. 09-993, 09-1039, 09-1501, 2011 WL 2874547, at *3–4 (U.S. July 18, 2011) (respondents' petition for rehearing);

Gardley-Starks v. Pfizer, Inc., 917 F. Supp. 2d 597, 607 (N.D. Miss. 2013); *Moretti v. PLIVA, Inc*., No. 2:08-CV-00396, 2012 WL 628502, at *2, 5 (D. Nev. Feb. 27, 2012), *aff'd sub nom. Moretti v. Wyeth, Inc*., 579 F. App'x 563 (9th Cir. 2014); *Moretti v. Mutual Pharm. Co*., 852 F Supp. 2d 1114, 1118 (D. Minn. 2012), *aff'd*, 518 F. App'x 486 (8th Cir. 2013); *Metz v. Wyeth, LLC*, No. 8:10-CV-2658, 2011 WL 5024448, at *4 (M.D. Fla. Oct. 20, 2011).

Second, even if Plaintiffs had pleaded a state-law "requirement" to stop selling (which they have not), the Supreme Court rejected a stop-selling argument in *Bartlett*. 570 U.S. at 488.

Third, no court has held that footnotes in *Bartlett* create an exception to preemption. *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.,* 756 F.3d 917, 928–30 (6th Cir. 2014) ("[I]t is not clear whether this language implies that an exception for 'parallel misbranding' claims actually exists."); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Prac. & Prods. Liab. Litig.,* No 3:09-md-02100, 2015 WL 7272766, at *3–4 (S.D. Ill. Nov. 18, 2015) (same). Moreover, even if they did create an exception, it would only apply to a "pure" design defect claim that did not consider the adequacy of the drug's labeling—and Plaintiffs have conceded they did not plead such a claim. *In re Darvocet,* 756 F.3d at 930; *In re Yasmin & Yaz,* 2015 WL 7272766 at *4; MDL.Dkt.1976:11,14,16; MDL.Dkt.1976:14; I.B, at 36–37.

Fourth, FDA actions in 2019 and 2020 do not alter the legal landscape; the agency never found ranitidine to be misbranded and, in any event, a violation of the misbranding statute may only be enforced by the FDA. *See* 21 U.S.C. § 337(a); *Buckman,* 531 U.S. at 352; MDL.Dkt.2499:137 (conceding that FDA "didn't technically go through the mandatory recall provision, and they didn't make a misbranding finding, and we never stated anything to the contrary.")

Lastly, this Court should reject Personal-Injury Plaintiffs' attempts to impose a new analytical framework for implied preemption based on "basic logic" or reliance on inapposite express preemption decisions and disregard the controlling analytical framework set in *Mensing* and *Bartlett*. This Court does not write on a blank slate. The "basic logic of conflict preemption" derives from the Supremacy Clause, *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992), and the Supreme Court has been interpreting that clause for centuries. Thus, it is inappropriate to assess a claim of implied preemption by relying on caselaw addressing express preemption. MDL.Dkt.2512:36–37.

The district court also correctly concluded that the AMPIC's claims against Generic Defendants are likewise preempted by federal law and that "sub-duties" are not "cognizable (and divisible) legal duties, let alone the duties to be used for comparison in federal pre-emption analysis." MDL.Dkt.3750:35. As this Court explained in *Guarino*, Personal-Injury Plaintiffs may not "attempt to elude"

impossibility preemption "by clothing" the allegations supporting their state-law claims in terms of new theories of liability. 719 F.3d at 1249. State law claims are preempted if, "at bottom," they rest on "allegations regarding" labeling or design defects that generic defendants could not have fixed while complying with the federal "duty of sameness." *Id.*; *see also Bartlett*, 570 U.S. at 486–87. That was the case here because Personal-Injury Plaintiffs' core theory remained that, due to ranitidine's molecular design, no ranitidine product is safe to ingest. In fact, Personal-Injury Plaintiffs' counsel conceded, ". . . we are not trying to say there is such a granular cause of action . . . It is still going to be just the general common law failure to warn . . ." MDL.Dkt.3683:181.

Moreover, accepting Personal-Injury Plaintiffs' invitation to judicially strike certain allegations within Personal-Injury Plaintiffs' causes of action violates well-settled limits of *Erie* principles because, by striking duties essential to the claims, the Court would be inventing new state-law claims. This it cannot do. *See Salinero v. Johnson & Johnson*, 995 F.3d 959, 966–67 (11th Cir. 2021).

The district court also faithfully applied this Court's precedents establishing that federal law impliedly preempts private efforts to enforce the FDCA, foreclosing Plaintiffs' failure-to-warn-through-FDA claim in the AMPIC. MDL.Dkt.3715:41–49; *see Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1329–30 (11th Cir. 2017); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348–53 (2001). The district

court's decision is also supported by *Mensing*, in which the Supreme Court held that the possibility of contacting FDA for assistance in warning cannot defeat generic-drug preemption of warnings-based causes of action. *See Mensing*, 564 U.S. at 611.

III. The District Court Appropriately Exercised its Gatekeeping Function by Excluding Experts Who Applied Improper Methodologies to Reach Flawed Conclusions

After extensive briefing and a two-day *Daubert* hearing, the district court granted defendants' *Daubert* motions and properly excluded Personal-Injury Plaintiffs' general causation experts. *See generally* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 595 (1993). The district court determined that plaintiffs' proffered experts "systemically utilized unreliable methodologies with a lack of documentation on how experiments were conducted, a lack of substantiation for analytical leaps, a lack of statistically significant data, and a lack of internally consistent, objective, science-based standards for the evenhanded evaluation of data." MDL.Dkt.6120:7.

In its 341-page *Daubert* decision, the district court acknowledged its "gatekeeping role to ensure that speculative and unreliable opinions do not reach the jury" by "consider[ing] *all* of the evidence relied upon by the Plaintiffs' experts . . . to determine whether the evidence reliably and helpfully informs the expert's general causation questions." MDL.Dkt.6120:135–36 (emphasis in original). After a detailed analysis of this evidence, the district court correctly determined that

"Plaintiffs have not met their burden to show that their experts relied upon any form of reliable primary evidence in support of their general causation opinions." MDL.Dkt.6120:321.[17]

Personal-Injury Plaintiffs argue that the district court exceeded its gatekeeping role by focusing on the experts' conclusions and ignoring the experts' reliance on the primary methodologies recognized in this Circuit.[18] The argument has no merit. The law has long recognized that an expert's ultimate conclusions are an integral part of the *Daubert* analysis. For a court to determine whether an expert's opinion reflects a reliable application of principles and methods, the court must undertake a review of the opinion itself. An expert's reliance on a primary methodology (and especially a faulty one as is the issue here) without more is not sufficient to withstand *Daubert*'s scrutiny.

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[17] The district court for the Southern District of Illinois reached similar conclusions in its recent 97-page opinion. *In re Paraquat Prod. Liab. Litig.*, No. 3:21-MD-3004, 2024 WL 1659687 (S.D. Ill. Apr. 17, 2024). In excluding the experts proffered by plaintiffs in that case, the court noted that "when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied." *Id.* at *40 (quoting Fed. R. Evid. 702 advisory committee's notes to 2000 amendment). The court also found further support in the fact that the proffered "causation theory has not been adopted or independently validated in any peer-reviewed scientific analysis outside of this litigation" and that is "an evidentiary red flag." *Id.* at *41.

[18] Personal-Injury Plaintiffs challenge the *Daubert* decision on other grounds, but those arguments are addressed in the Brand Defendants' brief.

A. The district court properly applied the *McClain* factors

This Court has observed that "toxic tort cases usually come in two broad categories: first, those cases in which the medical community generally recognizes the toxicity of the drug or chemical at issue, and second, those cases in which the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges." *McClain v. Metabolife Int'l, Inc*., 401 F.3d 1233, 1239 (11th Cir. 2005). "The court need not undertake an extensive *Daubert* analysis on the general toxicity question when the medical community recognizes that the agent causes the type of harm a plaintiff alleges." *Id.* This Court has provided the following as examples of the first type of case, often called a "category one" case: "toxins like asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; and cigarette smoke, which causes cancer." *Id.*

"In the second category of toxic tort cases, the *Daubert* analysis covers not only the expert's methodology for the plaintiff-specific questions about individual causation but also the general question of whether the drug or chemical *can* cause the harm plaintiff alleges." *Id.* (emphasis in original). So, for these "category two" cases, a court must assess the reliability of an expert's general causation opinion and specific causation opinion during the *Daubert* analysis. *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1303 (11th Cir. 2014).

Before the district court, Personal-Injury Plaintiffs argued (and still argue) that "a *component of ranitidine*—the NDMA *formed from ranitidine degradation*—is well known to be a carcinogen and, as a result, ranitidine falls into the first category of cases described in *McClain*." *See* MDL.Dkt.6120:26 (emphasis added). The district court disagreed and classified this case as a category two case for the *Daubert* analysis. MDL.Dkt.6120:28. The district court determined that "the facts in this MDL are not distinguishable from the facts in the published, binding *Fixodent* decision by the Eleventh Circuit";[19] but also that even if the *Fixodent* case was not binding, "the reasoning in the *Fixodent* cases is persuasive—the Plaintiffs must show that ranitidine consumption can result in sufficient NDMA ingestion to cause their alleged injuries." MDL.Dkt.6120:28. The district court also found that "Plaintiffs' position leads to untenable results," because "NDMA is a ubiquitous substance found in trace amounts in air, water, and food"; and "Plaintiffs have no reliable primary evidence on general causation," which "underscores the necessity for undertaking [the two-part] inquiry." MDL.Dkt.6120:28–29. The district court's reasoning is sound and without error.

Here, in this Court, it is illogical for Personal-Injury Plaintiffs to focus solely on NDMA, instead of ranitidine, for the analysis of the district court's opinion when

[19] *Chapman v. Procter & Gamble Distrib., LLC,* 766 F.3d 1296 (11th Cir. 2014).

they themselves have conceded the issue they allege is that ranitidine degrades over time into some unknown amount of NDMA. MDL.Dkt.6120:25–29.

B. The district court was mindful of its "critical" role as gatekeeper

District courts perform the "critical 'gatekeeping' function concerning the admissibility of expert scientific evidence." *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004). As this Court has explained, "***[t]he importance of Daubert's gatekeeping requirement cannot be overstated***." *Id.* (emphasis added). "The objective of that requirement is to ensure the reliability and relevancy of expert testimony." *Id*. (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). "The district court's role is especially significant since the expert's opinion 'can be both powerful and quite misleading because of the difficulty in evaluating it.'" *Id*. (quoting *Daubert*, 509 U.S. at 595). As this Court recognized in *Frazier*, the gatekeeping function is crucial because, aside from an expert, "no other kind of witness is free to opine about a complicated matter without any firsthand knowledge of the facts in the case." *Id*.

A qualified expert may present expert opinions if the proponent of the expert demonstrates that it is more likely than not that:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;

> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702.

With respect to reliability, "*Daubert* sets forth a non-exclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony." Fed. R. Evid. 702 advisory committee's notes to 2000 amendments. One factor courts consider during the *Daubert* analysis is "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion." Fed. R. Evid. 702 advisory committee's notes to 2000 amendments (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also id*. (explaining that this factor is "relevant to the determination of the reliability of expert testimony under the Rule"). Naturally, to determine whether an expert reaches an unfounded conclusion, the court must look to the conclusion itself as part of its analysis.

The Supreme Court "recognized, '***conclusions and methodology are not entirely distinct from one another***.'" Fed. R. Evid. 702 advisory committee's notes to 2000 amendments (quoting *Joiner*, 522 U.S. at 146) (emphasis added). As the advisory committee's notes to the 2000 amendments to Rule 702 explain:

> Under the amendment, as under *Daubert*, when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods

> have not been faithfully applied. *See Lust v. Merrell Dow Pharmaceuticals, Inc*., 89 F.3d 594, 598 (9th Cir. 1996). The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. As the court noted in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994), "*any* step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology*.

Id. (emphasis in original). Further, where an expert witness's experience is the claimed basis for reliability of that expert's opinion, "then the witness must explain how that experience leads to the conclusion reached." *Id*.

In each of these instances, to determine whether an expert's opinion reflects the reliable application of principles and methods to the facts of the case, the court must look at how the expert reached his or her conclusion and, of course, to the conclusion itself. "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" *Id*. (citing *Daubert*, 43 F.3d at 1319).

C. Rule 702 clearly defines a court's role in assessing expert testimony

Recently, Rule 702 was amended to clarify this critical gatekeeping function. The advisory committee's notes to the 2023 amendments state that:

> Rule 702(d) has also been amended to emphasize that ***each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology***. Judicial gatekeeping is essential because just as jurors may be unable, due to lack of

> specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support.

Fed. R. Evid. 702 advisory committee's notes to 2023 amendments (emphasis added). These amendments reaffirm that this vetting process requires an evaluation of how methodology is applied to reach a particular conclusion. As the 2023 Amendments make clear, "[n]othing in the amendment imposes any new, specific procedures." *Id*. "Similarly, nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, ***it does not permit the expert to make claims that are unsupported by the expert's basis and methodology***." *Id*. (emphasis added).

In their initial brief, Personal-Injury Plaintiffs criticize the district court's examination of their experts' conclusions and argue that the court should have focused on the experts' primary methodology only. But both the pre-amendment and current version of Rule 702 make clear that the district court was required to look at how the experts applied their methodologies to reach their conclusions to determine if this met the threshold reliability standard for expert testimony. *See Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998) ("[W]hile methodology remains the central focus of a *Daubert* inquiry, this focus

need not completely pretermit judicial consideration of an expert's conclusions. Rather, trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable."). Here, the district court's reliability analysis led it to the inevitable conclusion that the experts' unreliable methodologies caused untenable and inadmissible expert testimony.

In *Joiner*, the Supreme Court confronted (and rejected) a similar argument to the one Personal-Injury Plaintiffs make here:

> Respondent points to *Daubert*'s language that the "focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." 509 U.S. at 595, 113 S.Ct. at 2797. He claims that because the District Court's disagreement was with the conclusion that the experts drew from the studies, the District Court committed legal error and was properly reversed by the Court of Appeals. But conclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. *See Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360 (C.A.6), *cert. denied*, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992). That is what the District Court did here, and we hold that it did not abuse its discretion in so doing.

Joiner, 522 U.S. at 146. This Court should reach the same result here.

The district court's gatekeeping function is not about "taking sides," as Personal-Injury Plaintiffs submit. The district court was tasked with the critical role of determining whether Personal-Injury Plaintiffs' experts reliably applied proper methodologies to reach their various conclusions about general causation. In doing so, the district court determined that Personal-Injury Plaintiffs' experts "asserted methodological principles, then deviated from their own principles to rely upon studies that support their conclusions," and the experts "rel[ied] upon studies that do not support their conclusions," among other shortcomings. MDL.Dkt.6120:144. *See Guerrero v. BP Expl. & Prod. Inc.*, No. 8:20-CV-0263, 2024 WL 1244796, at *7 (M.D. Fla. Mar. 20, 2024) (excluding expert's general causation opinion as unreliable, where the expert's "conclusions regarding the association between petroleum and PAHs exposure and pancreatic cancer overstate what the studies bear out—thus his misplaced reliance on them calls his entire methodology into question" and where the "conclusions are unsupported by the studies [the expert] cites in his report"). Accordingly, the district court properly exercised its gatekeeping function by excluding Personal-Injury Plaintiffs' general causation experts.

IV. Personal-Injury Plaintiffs Forfeited Any Argument that the District Court Lacked Authority to Extend its Summary Judgment Ruling to Non-Brand Defendants

At an earlier stage of the litigation, Generic Defendants asked this Court to remand pending appeals to the district court so that the district court could extend its

summary judgment/*Daubert* ruling to those cases. CA11.Dkt.293. In response, Personal-Injury Plaintiffs argued that the district court lacked authority to grant such relief to non-Brand Defendants. CA11.Dkt.298. This Court granted Generic Defendants' motion to remand over Plaintiffs' objection. CA11.Dkt.333. On remand, the district court entered new judgments for Generic Defendants, based on preemption *and* lack of general causation.

Personal-Injury Plaintiffs' initial brief identifies six issues on appeal. I.B. at 10. None of those issues addresses the district court's extension of its *Daubert* ruling to Non-Brand Defendants, and Personal-Injury Plaintiffs nowhere contend that the extension constituted an abuse of discretion.[20] Instead, Personal-Injury Plaintiffs' 145-page brief includes only one sentence asserting that the district court "lacked authority" to extend its summary judgment ruling to non-Brand Defendants. I.B. at 80 ("As Appellants told this Court in motions' practice, the district court lacked authority to add a *new* ground under the federal rules.") (emphasis in original). That sentence comes at the end of a paragraph addressing the district court's decision to

[20] Personal-Injury Plaintiffs also do not raise any arguments concerning the extension of the district court's general causation ruling to Non-Designated Cancers. Any such arguments are now waived. *Anthony v. State*, 69 F.4th 796, 807 (11th Cir. 2023) ("Issues not raised in an initial brief are deemed forfeited and will not be addressed absent extraordinary circumstances.") (citing *Campbell*, 26 F.4th at 873. *See also Edwards v. Dothan City Schs.*, 82 F.4th 1306, 1314 n.2 (11th Cir. 2023) ("[I]ssues not raised in the initial brief on appeal are typically deemed abandoned.").

"grant[] summary judgment on claims against the non-Brand Defendants." *Id.* All but the last sentence of that paragraph purport to recite background facts and procedural history. *Id.* That sentence does not cite any authority, make any argument, or otherwise explain why this Court was wrong to reject the position Personal-Injury Plaintiffs set forth in earlier "motions' practice" addressing the same issue or how the district court abused its discretion.

Under the law of this Circuit, Personal-Injury Plaintiffs' conclusory and passing assertion that the district court lacked authority to extend its summary judgment ruling to non-Brand Defendants does not merit this Court's review. *See, e.g.*, *Anthony v. Georgia*, 69 F.4th 796, 807 (11th Cir. 2023); *Sapuppo v. Allstate Floridian Ins. Co.*, 739 F.3d 678, 682 (11th Cir. 2014) (explaining that "[a]bandonment of an issue" can occur when the opening brief makes only "passing references" to the issue, particularly when those passing references consist of "nothing more than conclusory assertions"). Furthermore, this Court rejected Personal-Injury Plaintiffs' position when it granted non-Brand Defendants' motion to remand so that the district court could extend its general causation ruling to non-Brand Defendants. Personal-Injury Plaintiffs offer no basis—much less a new basis—for revisiting that ruling now, and the Court should adhere to its earlier ruling even if it elects to consider Personal-Injury Plaintiffs' forfeited argument. *See* CA11.Dkt.293; CA11.Dkt.298; CA.11.Dkt.301; CA11.Dkt.303.

V. The District Court Followed the Proper Procedure to Apply Its *Daubert* Ruling to All MDL Plaintiffs

The district court afforded each plaintiff in the MDL with due process before applying its dispositive *Daubert* ruling to the individual plaintiffs, regardless of when the plaintiff joined the MDL, because the district court properly utilized a universally accepted procedure to ensure that each plaintiff was given notice and the opportunity to show why the court's general causation findings should not apply to their individual case before entering judgment against them.

In multidistrict litigation, the transferee court is tasked with coordinating cases for pretrial proceedings. 28 U.S.C. § 1407. Indeed, "[t]he MDL process requires a judge to move hundreds or thousands of cases towards resolution while respecting each litigant's individual rights," including due process. *Home Depot USA, Inc. v. Lafarge N. Am., Inc.*, 59 F.4th 55, 65 (3d Cir. 2023). Given the enormity of the task the MDL court is faced with, MDL judges have developed "efficient, effective, and fair case management techniques" to safeguard the procedural values of each individual case while simultaneously pursuing an efficient resolution on the merits. *Id.*

One of the techniques MDL courts have repeatedly used is a dual approach with a case management order that provides notice of the MDL court's intention to apply a decision across parties followed with an order to show cause process that allows any parties to come forward and show why the ruling should not be applicable

to them. *See, e.g.,* Order of Jan. 24, 2018, *In re Terrorist Attacks on Sept. 11, 2001*, No. 03-MD-1570, at 2 (S.D.N.Y. Jan. 24, 2018) ("Any order entered into, or decision rendered, in this MDL that relates to all actions shall apply to all Tag-Along Actions without the need for separate motions and orders, unless counsel in a Tag-Along Action show good cause why the order should not apply to that Tag-Along Action."); Order to Show Cause as to the B3 Claims Against the Clean-Up Responder Defendants, *In re Oil Spill by the Oil Rig Deepwater Horizon*, No. 10-MD-2179 (E.D. La. Jan. 7, 2016) (similar); Order No. 50, *In re Gen. Motors LLC Ignition Switch Litig.*, No. 14-MD-02543, at 8 (S.D.N.Y. Apr. 24, 2015) (implementing a show-cause procedure for applying rulings made on the basis of consolidated pleadings to non-consolidated actions). Appellate courts have repeatedly held that this is a valid procedure to help MDL courts balance the herculean task of managing thousands of cases while ensuring that each individual case is treated fairly. *See, e.g., Home Depot*, 59 F.4th at 66.

A. The district court correctly utilized the order to show cause procedure and Personal-Injury Plaintiffs agreed to it

The district court provided ample notice that it intended to hear and rule on general causation initially because whether or not ranitidine caused cancer affected all plaintiffs regardless of whether the plaintiffs took brand or generic

ranitidine.[21] In fact, Personal-Injury Plaintiffs agreed to this procedure at the May 2020 initial case management hearing. MDL.Dkt.960:188–89 ("Basically, in a nutshell it is this: General causation, *Daubert* briefing, and that decision on general causation is going to precede the selection of bellwether and individual case workup."). At the same hearing, it was clear that the parties believed that the "threshold question" was whether ranitidine could cause cancer. MDL.Dkt.960:162. Reflecting the parties' understanding of the case, the court's case management order states that "[t]he Court adopts the parties' proposed schedule that a hearing on *Daubert* challenges on general causation will precede bellwether selection, and general causation *Daubert* motions shall be filed 18 months following the initiation of discovery." MDL.Dkt.1194:2. Personal-Injury Plaintiffs cannot withdraw their consent to this procedure because they did not get their desired results. *See Hoffman v. De Marchena Kaluche & Asociados*, 657 F.3d 1184, 1187 (11th Cir. 2011) ("As

[21] There is no basis to assert that the general causation bar would be lower to support a claim against a generic manufacturer than against a branded manufacturer. The lack of reliable studies demonstrating an increased risk of any cancer in humans taking ranitidine is fatal to both. Indeed, given the broad scope of preemption as to claims against generic manufacturers, any claim based on a purported deviation of a particular lot, shipment, or container of ranitidine would require proof of causation for comparable levels of exposure. *See Joiner*, 522 U.S. at 146; *Moore v. Ashland Chemical Inc.*, 151 F.3d 269, 278-79 (5th Cir. 1998). Plaintiffs' experts failed to identify reliable studies demonstrating an increased risk even with several years of use of ranitidine.

a general rule, a party has no standing to appeal an order or judgment to which he consented.") (citation omitted).

B. Personal-Injury Plaintiffs failed to provide new evidence

Further, Personal-Injury Plaintiffs' claims that the district court failed to recognize and fulfill certain due process concerns is contradicted by the record in this case. To the contrary, the district court repeatedly gave Personal-Injury Plaintiffs meaningful opportunities to come forward to explain why the orders should not be applied to be them. Indeed, the district court entered at least four separate orders to show cause that detailed the process for all plaintiffs, including later-filed plaintiffs, to respond with any reasoning to support why the court's orders should not be applied to their individual cases. MDL.Dkt.6303; MDL.Dkt.6444; MDL.Dkt.6639; MDL.Dkt.6642. No Personal-Injury Plaintiff came forward with any evidence to explain why the ruling should not be applied. *See generally* 20-md-2924.

The agreed-to process used by the district court comports with the Supreme Court's finding that "[t]he fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (internal quotation marks and citation omitted). Due process does not—and cannot—require a court to force individuals to present one's case. Instead, the court need only provide a meaningful opportunity

to do so. *See, e.g., Home Depot*, 59 F.4th at 66, n.6 ("In MDLs, like in other litigation, a district court may apply prior rulings to new cases if a party presents no new facts, evidence, or arguments to warrant a departure."). The district court clearly provided plaintiffs with ***repeated*** meaningful opportunities to be heard.

C. The district court's procedures were not unique

Contrary to what Personal-Injury Plaintiffs now claim, the application of a *Daubert* order to all plaintiffs is not without precedent. In *Mirena IUD Products Liability Litigation*, the district court was faced with the question of whether there was any other evidence that would allow the case to continue after excluding the bellwether plaintiffs' expert opinion on general causation. 202 F. Supp. 3d 304, 327–28 (S.D.N.Y. 2016). The *Mirena* court entered summary judgment in favor of defendants because "[h]aving excluded Plaintiffs' expert opinion on general causation, and having concluded that there are no admissions that can substitute for such opinion, and there being no dispute that all claims rise or fall with that decision" no reasonable jury could find in favor of the plaintiffs. *Id*. The decision was not solely limited to the bellwether plaintiffs. *Id.* Rather, the *Mirena* court understood that its decision would be applied to *all of the cases* in the litigation. *Id.* at 328. ("The Court reaches this conclusion reluctantly, ***knowing that it will doom hundreds of cases***, but in the Court's view it is compelled by the law.") (emphasis added). This is simple logic. It does not make sense to continue with other cases if the plaintiffs

have ***failed to show that there could be any link*** between the complained-of product and the resulting injury. It would only allow parties to continue to litigate an issue that the court has already decided. Similarly, here, the district court determined that there was no reason to continue to move forward any of the cases if there was no evidence to support that ranitidine could be causally connected to the plaintiffs' injuries.

Further, the case Personal-Injury Plaintiffs rely upon is easily distinguished and, in fact, supports what the district court did in this case. In *Acetaminophen-ASD-ADHD Products Liability Litigation*, the court granted the defendant's *Daubert* motions, excluding the plaintiff leadership's general causation experts. Case No. 22-mc-3043, Doc. 105 (S.D.N.Y. Feb. 16, 2024). The court then issued an order to show cause asking all the plaintiffs in the MDL why judgment should not be entered in their individual cases given its general causation ruling. *Id.* Unlike the individual plaintiffs in this case, a subset of plaintiffs in five member cases of the *Acetaminophen* MDL came forward with new evidence and a new expert to support their claims that acetaminophen causes ADHD. *Id.* In fact, the plaintiffs attached the expert's report to their response to the order to show cause. *Id.* The *Acetaminophen* court was simply following the same order to show cause process used in the ranitidine litigation. That process allowed other plaintiffs in the MDL to bring forth new experts when there was concrete evidence of causation. Here,

Personal-Injury Plaintiffs failed to come forward with an expert report or new evidence. Thus, the district court was not presented with any substantive evidence that would require it to reevaluate its decision.

Accordingly, the district court properly followed an established process to apply its *Daubert* ruling to Personal-Injury Plaintiffs. The district court and all parties agreed that general causation was a threshold issue and would have to be determined first before any bellwether trials could occur. The parties were able to thoroughly brief the issue of general causation before the court. After the court determined there was no evidence of general causation, the court then issued a series of orders to show cause to provide Personal-Injury Plaintiffs with several opportunities to come forward to present evidence as to why the ruling should not be applied to them. The district court followed an accepted procedure to ensure that each Personal-Injury Plaintiff was afforded due process while balancing the difficult task of managing thousands of cases through the pretrial process. Accordingly, this Court should affirm the district court's decision applying the *Daubert* decision across the plaintiff group.

CONCLUSION

The district court had diversity jurisdiction over the cases in this MDL. It properly considered the allegations against the Generic Defendants asserted in the MPIC and AMPIC and found them preempted by federal law and the duty of sameness that underpins the entire generic industry. Then, it carefully considered the general causation experts proffered by Personal-Injury Plaintiffs. It found that those experts did not faithfully apply their methodologies to their opinions and therefore offered improper and unreliable testimony. Through a vigorous order to show cause process, the district court offered Personal-Injury Plaintiffs multiple chances to come forth with additional evidence, and when none was provided, the court determined that its general causation ruling should apply to all defendants in this MDL. The dismissal of these cases by the district court warrants affirmance.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation allowed by this Court's Order (CA.11.Dkt.137-1) because it contains 13,594 words, excluding the parts exempted by Fed. R. App. P. 32(f). This brief complies with the typeface requirements of Fed. R. App. P. 32(a) because it has been prepared in a proportionately spaced typeface using Microsoft Word Times New Roman 14-point font.

Date: July 26, 2024 */s/ Thomas J. Yoo*

CERTIFICATE OF SERVICE

On July 26, 2024, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. All participants in this case are registered CM/ECF users, and service will be accomplished by the CM/ECF system.

/s/ Thomas J. Yoo